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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,781	06/13/2007	Steven Gary Kendrew	0380-P04094US0	5863

110 7590 10/28/2008
DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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10/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,781	Applicant(s) KENDREW ET AL.	
	Examiner IQBAL H. CHOWDHURY	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Supplemental Election/Restrictions

The instant Office Action is a supplemental restriction requirement. The previous Office action mailed on 05/13/2008) [a restriction requirement for a substrate of deubiquitinating enzyme and method of use thereof]. This supplemental restriction requirement is at the discretion of the Examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary in view of the identification of typographical error in groupings of inventions.

The previous Restriction requirement mailed on 05/13/2008 is hereby withdrawn.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group, I claim(s) 1-31, drawn to a method for generating hydroxylated 14-membered macrolide compounds comprising producing 14-membered aglycone template and feeding said aglycone template to a natural or recombinant host cell, wherein said host cell comprises P450 hydroxylase gene derived from *Streptomyces eurythermus* strain capable of hydroxylating the aglycone template at the 14 and/or 15 position.

Groups, II claim(s) 1-31, drawn to a method for generating hydroxylated 14-membered macrolide compounds comprising producing 14-membered aglycone template and feeding said aglycone template to a natural or recombinant host cell, wherein said host

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cell comprises P450 hydroxylase gene derived from *Streptomyces avermitilis* strain capable of hydroxylating the aglycone template at the 14 and/or 15 positions.

Groups, III claim(s) 1-31, drawn to a method for generating hydroxylated 14-membered macrolide compounds comprising producing 14-membered aglycone template and feeding said aglycone template to a natural or recombinant host cell, wherein said host cell comprises P450 hydroxylase gene derived from *Streptomyces rochei* strain capable of hydroxylating the aglycone template at the 14 and/or 15 positions.

Groups, IV claim(s) 32-37, drawn to a compound of formula I of claim 32.

2. The inventions listed as Groups I – IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The strains used in the method of Groups I-III are unrelated to each other because each strain comprises unrelated chemical structure, and unrelated bio-molecules, which are structurally and functionally different, independent and distinct. The only shared technical feature of these groups is that they all relate to polynucleotide encoding a polypeptide cytochrome P450 hydroxylase, which hydroxylates aglycone compound at certain position. However, this shared technical feature is not a “special technical feature” as defined by PCT Rule 13.2 as it does not define a contribution over the art. According to the search report (PCT form 210), a DNA encoding a cytochrome p450 hydroxylase protein is known in the art (Gaisser et al. “Parallel pathways for oxidation of 14-membered polyketide macrolactones in *Saccharopolyspora erythraea*, Mol microbiology (2002),

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44(3):771-781; Xue et al. PNAS, 1998, 95:12111-12116; and US PGPUB 2003/0203425, see IDS, and US 6902913 B2, issued on 6/7/2005, claim priority of 60/087,080 filed on 5/28/1998), as well as process for producing hydroxylated 14-membered polyketide aglycone in host cell expressing said cytochrome p450 hydroxylase gene. Thus, microorganism comprising a DNA encoding a cytochrome p450 hydroxylase protein does not make contribution over the prior art. Thus, all the inventions lack unity of invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election/Restrictions/Species

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This application also contains claims directed to many patentably distinct **species** of the claimed invention of genus of a compound recited in claim 19 having R1-R14, and X, wherein each of the R groups and X group has many variables. Applicants are advised to elect a single species for each R groups and X group including R15-R22 for claims 19, 21, and 28.

The methods comprising each of the species of compounds does not have unity of invention between each other because each method comprises unrelated steps, use different products and produce different effects (end products). Besides, the compounds used in the method as defined in claims 19, 21, and 28 are unrelated. In the instant case the different inventions represent structurally different compounds. Therefore, where structural identity is required, such as for antibody binding, the different compounds have different effects.

Applicant is required under 35 U.S.C. 121 and 372 to **elect a single disclosed species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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